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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,208	12/01/2003	Jon Elliot Adler	T1530-00025	9851

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HUNTON & WILLIAMS LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
1900 K STREET, N.W.  
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WASHINGTON, DC 20006-1109

EXAMINER
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BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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05/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/724,208	<b>Applicant(s)</b> ADLER, JON ELLIOT	
	<b>Examiner</b> Michael Brannock	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 173-223 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 173-223 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application: Claims and Amendments***

Applicant is notified that the amendments put forth on 2/15/2007, have been entered in full. Further, Applicant is notified that any prior objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments, and, more specifically to Applicant's persuasive arguments regarding the definitiveness of the word "putatively" as it is used in the claims and commonly understood in the art of receptor pharmacology.

### ***Information Disclosure Statement***

As set forth previously, the information disclosure statement filed 3/16/2004 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

### ***Specification***

As set forth previously, the disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 17 and 37 for example. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP 608.01.

### ***Claim Objections***

Claim 173 is objected to because of the following informalities: the claim utilizes numbers, i.e. (1) and (2), to designate subsections of an already numbered claim. It is recommended that the designations (i) and (ii) be used, as per claim 197.

Claim 197 is objected to because of the following informalities: it appears that the word/letter “a” is missing between “to” and “bitter” in line three of the claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 173-223 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the following reasons.

The claims require “the polypeptide contained in SEQ ID NO: 8”; this phrasing is confusing and it is unclear how the polypeptide is contained, thus the metes and bounds of the claims cannot be determined. It is suggested the phrase “the polypeptide of SEQ ID NO: 8” be used if this is consistent with Applicant’s intended meaning. Similarly, claim 173 recites the phrase “the nucleic acid sequence in SEQ ID NO: 7”; this phrasing is confusing and it is unclear how the nucleic acid sequence is “in” SEQ ID NO: 7, thus the metes and bounds of the claims cannot be determined. It is suggested the phrase “the nucleic acid sequence of SEQ ID NO: 7” be used if this is consistent with Applicant’s intended meaning.

Claims 184-188 and 202-204 require that the method be practiced whereby the polypeptide is expressed by a cell; this is confusing because one skilled in the art would not know if it is required that the polypeptide is only to be expressed by a cell and then subsequently purified to be used in the assay or that the polypeptide must be in the cell during the assay. Appropriate clarification or correction is required.

Claim 217 requires that the binding assay detects changes in “hydrodynamic characteristics or solubility”. This phrase renders the claims indefinite for several reasons. First there is no definition as to what “hydrodynamic characteristics” are and what they are not. The specification only identifies them by way of example “e.g. shape” [0079], which is not sufficient to establish the metes and bounds of the claim; thus the artisan could not be sure that he or she were practicing the claimed invention.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 204, 210, 216 and 217 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 204 requires a "BHK" cell, there is no mention of such in the application as filed. Claim 210 requires an assay that measures the effect of a compound on the activation of the receptor by detecting the effect of the compound on the transcription of the receptor, yet there is no disclosure of such in the application as originally filed. Claim 216 requires that the activation of the receptor be monitored while the receptor is in solution, yet there is no disclosure of this in the application as originally filed. Claim 217 requires that the activation of the receptor be measured via changes in hydrodynamic properties such a solubility changes, yet there is no teaching of this in the specification as filed. This is a new matter rejection.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



May 8, 2007



JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER